ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42082 (FRL-3031-2)]

Toxic Substances, 1,1-Dichloroethylene; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing that manufacturers and processors of 1,1-dichloroethylene [CAS No. 75-35-4] be required, under section 4 of the Toxic Substances Control Act (TSCA), to conduct distribution, excretion and metabolism (DEM) studies and a two-year inhalation oncogenicity bioassay in mice. The Agency proposes to delay the initiation of the oncogenicity testing until after the DEM data have been completed and evaluated.

DATES: Submit written comments on or before October 14, 1986. If persons request an opportunity to submit oral comment by September 26, 1986, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting see Unit VIII of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42082), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460, Toll free: (800-424-9065), In Washington, DC:

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(554–1404). Outside the USA: (Operator—202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Chemical Recommendation

1,1-Dichloroethylene (vinylidene chloride) was recommended for testing by EPA's Office of Air Quality Planning and Standards. The chemical had been considered for regulation as a potentially toxic air pollutant under the Clean Air Act, but the decision was made not to regulate at that time (50 FR 32632; August 13, 1985). This decision was made because the available information was insufficient to support a decision to regulate, although some data suggest that this chemical may be an oncogen. The Agency proposes to use the testing authority of section 4 of TSCA to obtain data needed to better assess the oncogenic potential of 1,1-dichloroethylene.

B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA shall by rule require testing of a chemical substance or mixture to develop appropriate test data if the Agency finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the findings under section 4(a)(1)(A)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to the chemical. In making the finding under section 4(a)(1)(A)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's approach to determining when these findings apply is described in detail in its first and second proposed test rules, published in the **Federal Register** of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300).

In evaluating the testing recommendations for 1,1-dichloroethylene, EPA considered all available relevant information, including published and unpublished data available to the Agency. From its evaluation, EPA is proposing health effects testing requirements for 1,1-dichloroethylene under section 4(a)(1)(A).

II. Review of Relevant Data

Most of the following material has been reviewed by the Environmental Protection Agency in a published Health Assessment Document (Ref. 1).

1,1-Dichloroethylene production capacity in the United States is approximately 150 million pounds per year (Economic Analysis Support Document). Virtually all of the chemical produced is used in the production of polymers. About 4 percent of 1,1-dichloroethylene is used as a chemical intermediate for non-polymer products.

Because of its high volatility, 1,1-dichloroethylene is lost to the atmosphere during manufacture of the monomer and polymer. The estimated total emission to all media from manufacturing and processing facilities is 1.3 million pounds per year. The estimated median ambient air level in urban/suburban areas of the U.S. is 0.005 parts per billion (ppb). However, for ambient air in the vicinity of point sources of emission the measured median concentration value is substantially higher (2.2 ppb). The estimated population residing within 5 miles of plants producing or processing 1,1-dichloroethylene totals 3.6 million (Ref. 1).

EPA has evaluated 18 chronic studies in animals for evidence of oncogenicity. Positive results were seen in one inhalation study (Ref. 2). "Swiss" mice were exposed to 10 or 25 parts per million (ppm) 1,1-dichloroethylene 4 hours per day, 4 to 5 days per week for 52 weeks. The experiment was terminated at 126 weeks. A significant increase in kidney adenocarcinomas was observed in male mice at 25 ppm, but not at 10 ppm or in controls. Mice were also exposed at higher dose levels, 200, 100 and 50 ppm, but exposure was discontinued because of toxicity after 2 days at the two highest doses, and after 1 week at 50 ppm. These animals were held for the remainder of the 126-week experiment. No renal adenocarcinomas were seen in the animals at 200 or 100 ppm exposure, but two were seen at the 50 ppm level. This study by Maltoni et al. was considered by EPA to provide limited evidence of animal oncogenicity (Ref. 1).

The remaining 17 animal bioassays provide no evidence of oncogenicity. All but one of these studies had significant flaws in design. These included studies in three species (mouse, rat, hamster) by five routes of administration (gavage, ingestion, inhalation, skin-painting, subcutaneous (sc) injection). The Chinese hamster study was by inhalation at the same doses and under the same conditions seen in the mouse study discussed earlier (Ref. 2). The five mouse studies which showed no oncogenic effect used four different strains of mice ($B6C3F_1$, CD, CD–1, Ha-ICR) by four routes of administration (gavage, inhalation, skin-painting, sc injection). The 11 rat studies utilized four different strains of rat (Fischer 344, Sprague-Dawley, CD, Wistar) by three different routes of administration (gavage, ingestion, inhalation).

Exposure to the chemical in these studies ranged from a minimum of one month in two inhalation studies in rats and mice, with 13 months observation, to a maximum of lifetime exposure in the skin-painting and sc injection studies in mice. However, the skin-painting study only included three applications per week and the sc injection study only treated the animals once a week.

The negative findings in these studies may be partially explained by study characteristics such as: dosing regimens of less than 2 years duration; less than a maximally tolerated dose; differences in routes of administration; and testing at a single dose level. These limitations individually or in combination reduce the sensitivity of detecting a positive response (Ref. 1).

The only study considered by EPA to have an adequate protocol to demonstrate a chemical's lack of oncogenic potential was the National Toxicology Program's (NTP) two-year gavage study of 1,1-dichloroethylene in F344 rats and $B6C3F_1$ mice (Ref. 3).

However, this study may not have achieved a sufficiently high dose. Although chronic renal inflammation was seen in high-dose (5 mg/kg) rats of both sexes and increased necrosis of the liver appeared in high-dose (10 mg/kg) male mice and low-dose (2 mg/kg) female mice, no effects on weight or survival on either sex of either species were observed. While the cumulative dose of the NTP high-dose mouse gavage study (130 mg) and the Maltoni 25 ppm mouse inhalation group (112.5 mg) are roughly equivalent, there is a possibility that the route of administration and the strain of mouse used made a difference in the results because of differences in distribution and metabolism in the tissue or if normal metabolic routes are overcome. Further discussion of these areas is detailed in Unit IV.

The authors of an epidemiologic study of 1,1-dichloroethylene (Ref. 4) concluded that it showed no oncogenic effect attributable to the chemical. EPA has reviewed the study (Ref. 1) and has determined that the population examined in this study may be too small to evaluate oncogenic potential for a weak oncogen.

EPA has reviewed several other studies that provide suggestive evidence of 1,1-dichloroethylene's oncogenic potential (Ref. 1). These include several positive responses in bacterial and yeast mutagenicity studies, one positive plant mutagenicity study, binding of 1,1-dichloroethylene to mammalian DNA, and an increase in unscheduled DNA synthesis in mammalian cells. 1,1-Dichloroethylene also acted as an initiator in a mouse skin-painting study, although it did not act as a complete oncogen. Finally 1,1-dichloroethylene is structurally related to a known human oncogen, chloroethylene (vinyl chloride).

III. Findings

EPA finds under TSCA section 4(a)(1)(A) that the manufacture and processing of 1,1-dichloroethylene and its subsequent inhalation by the population living near manufacturing and processing plants may present an unreasonable risk of oncogenicity. These findings are based on: (1) The positive evidence of oncogenicity for 1,1-dichloroethylene in the Maltoni study; (2) its mutagenicity in several test systems; (3) its interaction with DNA; (4) its activity as a tumor initiator; and (5) its structural relationship to chloroethylene. The Agency also finds that available data, as described in Unit II, are not sufficient to reasonably determine or predict the effects to human health of exposure to 1,1-dichloroethylene and that testing is necessary to develop such data.

IV. Proposed Rule

A. Proposed Testing and Test Standards

The Agency is proposing that comparative DEM studies be done as specified in 40 CFR 798.7475 as published in the **Federal Register** of November 6, 1985 (50 FR 46116). These studies shall be done in two mouse strains, the "Swiss" strain used by Maltoni (Ref. 2) and the B6C3F$_1$ strain used by the NTP (Ref. 3). The DEM tests are being proposed because of the differences in protocol and outcome between the negative in the gavage NTP and the positive in the Maltoni inhalation studies. The Maltoni study (Ref. 2) showed renal adenocarcinomas, as well as liver and kidney toxicity in mice. In the mice used for the NTP study only hepatotoxicity was seen (Ref. 3). It may be that the "Swiss" mice used by Maltoni are more sensitive than other strains of mice. It may also be that the maximum tolerated dose was not attained in the NTP study. Furthermore, it is known that differential toxicity may occur as a result of different routes of administration. With dichloromethane, for example, lung oncogenicity was seen in animals exposed by inhalation, but not in those treated orally. Some evidence suggests that differences in the route of administration may be significant for 1,1-dichloroethylene as well. Oral and inhalation exposures are associated with greater distribution of 1,1-dichloroethylene to the liver and kidney, respectively. The influence of these differences in distribution upon potential oncogenic responses are unknown. For 1,1-dichloroethylene, the one gavage study in mice (Ref. 3) may or may not have been adequate, but all three of the known mouse inhalation studies are known to be inadequate, in part because of insufficient periods of exposure and/or observation. However, one of these studies, the Maltoni bioassay (Ref. 2), did give a positive oncogenicity response.

The proposed DEM tests should determine if metabolic and disposition differences due to the strain of mouse or the route of administration may account for the differences in the results of the existing bioassays. The results will be used in decision-making and to aid in the design of the oncogenicity bioassay.

EPA is also proposing that an oncogenicity test be conducted on 1,1-dichloroethylene in accordance with the TSCA test guidelines for oncogenicity specified in 40 CFR 798.3300, published in the **Federal Register** of September 27, 1985 (50 FR 39252) and modified as proposed in the **Federal Register** of January 14, 1986 (51 FR 1522). This testing shall be performed with the "Swiss" mouse, because of its demonstrated sensitivity, and the route of exposure shall be by inhalation.

B. Test Substance

The proposed test substance is 1,1-dichloroethylene (CAS No. 75-35-4), of at least 99.8 percent purity, which is a commercially available grade.

C. Persons Required To Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Agency makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal.

Because EPA has found that existing data and experience are insufficient to reasonably determine or predict the effects of the manufacture or processing of 1,1-dichloroethylene on the potential for oncogenicity, the Agency is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process 1,1-dichloroethylene at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time after the submission of the last final report required under the test rule equal to that which was required to develop data, if more than 5 years.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate on such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for 1,1-dichloroethylene. The EPA is interested in evaluating the effects attributable to 1,1-dichloroethylene itself and has specified a nearly pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

D. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) standards which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans no later than 45 days before the start of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is proposing that the DEM testing be completed and the final report submitted to EPA within 15 months of the effective date of this test rule. The oncogenicity testing shall be completed and the final report submitted to EPA within 68 months of the effective date of this test rule. Progress reports for each proposed test are required at 6-month intervals starting 6 months from the effective date of the final test rule.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) appear in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of 1,1-dichloroethylene must report to EPA the first annual export or intended export of 1,1-dichloroethylene to any one country. EPA will notify the foreign country about the test rule for the chemical.

E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated EPA representatives to determine compliance with any final rule for 1,1-dichloroethylene. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, and that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.28(b)). Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Issues for Comment

1. Are the existing studies of 1,1-dichloroethylene's oncogenic potential adequate to assess the risks of exposure to this substance?

2. The Agency is proposing both the DEM studies and the inhalation bioassay at this time. EPA is requiring the DEM work to be completed before the bioassay is initiated, and the results of the earlier tests to be used to help design the bioassay. Are the DEM studies appropriate for this purpose? Should be bioassay be finalized only after review by the Agency of the DEM results, to allow EPA to include necessary modifications? Will the DEM studies be useful in helping address the need for the bioassay?

3. The Agency is basing the need for a further oncogenicity bioassay in mice on the differential response that can be seen in animal bioassays depending on the route of exposure. EPA solicits comments on this justification.

4. Should EPA require an epidemiology study for 1,1-dichloroethylene in lieu of a 2-year animal bioassay, and can appropriate cohorts be identified? While EPA considers the Ott study (Ref. 4) to be inadequate to determine that 1,1-dichloroethylene is not a human oncogen, it is possible that a well-designed study with a sufficient number of workers followed for a long enough time may be a better choice for evaluating the possible oncogenicity of the compound.

5. Because of the narrow range of toxicity of 1,1-dichloroethylene (Ref. 2) and the lack of positive results seen in most of these bioassays, some modifications to these studies have been considered. Among the possible changes are an increase in the size of the groups to increase the power of the bioassay, particularly at lower doses. The compound is known to have a shorter half-life in the body than some of the other chlorinated ethylenes (e.g., tetrachloroethylene), and using a lower dose while increasing the daily time of exposure to a greater proportion of a 24-hour day would more realistically represent the type of human exposure upon which this proposed rule is based (persons living in the vicinity of the manufacturing or processing plants). The third possible alteration also deals with this exposure problem. Should EPA consider exposing the animals in utero and beyond through exposure of the dams, and/or exposing them to the chemical directly at a younger age? The Agency requests comments on these possible modifications to the proposed testing.

6. Should EPA require that two species be tested in the oncogenicity study in conformance with the Agency's normal test guidelines or are adequate data now available to indicate that the mouse is the most sensitive species and that testing should be limited to that species? In addition, is the "Swiss" mouse the most appropriate strain in which to perform the inhalation bioassay?

VI. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis. This consists of evaluating each chemical or chemical group on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis, along with the consideration of the costs of the required tests, indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for the chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

Total testing costs for the proposed rule for 1,1-dichloroethylene are estimated to range from $734,990 to $959,308. The estimated costs for the comparative oral and inhalation DEM studies for this test rule range from $144,613 to $191,673, while the costs for the other proposed testing, the mouse inhalation bioassay, range from $590,376 to $767,634. The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from $190,448 to $248,573. Based on the estimated 1984 production of 150 million pounds, the unit test cost is 0.17 cent per pound. In relation to the current list price of 30 to 37 cents per pound for 1,1-dichloroethylene, this cost is equivalent to 0.45 to 0.55 percent of unit value.

The Level I economic analysis indicates that the potential for adverse economic effects due to the estimated test cost is low. This condition is based on the following observations: (1) Demand for 1,1-dichloroethylene appears relatively inelastic owing to its dominant use as a captive intermediate; (2) the market expectations for 1,1-dichloroethylene are optimistic; and (3) the estimated unit test costs are very low. A Level II analysis is not necessary.

VII. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the NTIS (PB 82-140773). On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

VIII. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, D.C. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-9065); In Washington, D.C.: (554-1404); Outside the U.S.A. (Operator—202-554-1404), by September 26, 1986. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

IX. Public Record

EPA has established a record for this rulemaking, (docket number OPTS-42082). This record contains the basic information considered by the Agency in developing this proposal and appropriate Federal Register notices.

This record includes the following information:

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A. Supporting Documentationn

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Air Pollution Control; Decision Not To Require Vinylidene Chloride and Solicitation of Information (50 FR 32632; August 13, 1985).

(b) Notice of final rule on EPA's TSCA good laboratory practice standards (48 FR 53922; November 29, 1983).

(c) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(d) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).

(e) Toxic Substances Control Act Test Guidelines; Final Rules (50 FR 39252; September 27, 1985).

(f) Revisions to the Toxic Substances Control Act Test Guidelnes Proposed Rule (51 FR 1522; January 14, 1986).

(2) Support document consisting of 1,1-dichloroethylene's economic analysis.

(3) Communications before proposal; contact report of telephone coversation.

B. References

(1) U.S. Environmental Protection Agency. "Heath Assessment Document for Vinylidene Chloride". Washington, DC: Office of Health and Environmental Assessment. EPA Report No. 600/8-83-031F (1985).

(2) Maltoni, C., Lefemine, G., Chieco, P., Cotti, G., and Patella, v. *Experimental Research on Vinylidene Chloride Carcinogenesis*. Princeton, N.J.: Princeton Scientific Publishers, Inc. (1985).

(3) National Toxicology Program. "NTP Technical Report on the Carcinogenesis Bioassay of Vinylidene Chloride (CAS No. 75-35-4) in F344/N Rats and B6C3F$_1$/N Mice (Gavage Study)". Washington, DC: National Toxicology Program. NIH Publication No. 82-1784 (1982).

(4) Ott, M.G., Fishbeck, M.D., Townsend, J.C. and Schneider, E.J. "A Health Study of Employees Exposed to Vinylidene Chloride". *Journal of Occupational Medicine* 18: 735-738 (1976).

X. Other Regulatory Requirements

A Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) They are not expected to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070-0033. Submit comments on these requirements to the Office of Information and Regulatory Affairs: OMB; 728 Jackson Place, NW., Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

Testing Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements.

Dated: August 4, 1986.

Victor J. Kimm,

Acting Assistant Administrator, for Pesticides, and Toxic Substances.

PART 799—[AMENDED]

Therefore it is proposed that 40 CFR Part 799 be amended as follows:

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By adding § 799.1545 to read as follows:

§ 799.1545 1,1-Dichloroethylene.

(a) *Identification of test substance.* (1) 1,1-Dichloroethylene (CAS No. 75-35-4) shall be tested in accordance with this section.

(2) 1,1-Dichloroethylene of at least 99.8-percent purity shall be used as the test substance.

(b) *Person required to submit study plans, conduct tests, and submit data.* (1) All persons who manufacture or process 1,1-dihloroethylene, other than as an impurity, from the effective date of this section (44 days after the publication date of the final rule in the **Federal Register**) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests in accordance with Part 792 of this chapter, and submit data as specified in this section, Subpart A of this Part, and Part 790 of this chapter.

(c) *Health effects*—(1) *Distribution, excretion and metabolism*—(i) *Required testing.* (A) Distribution, excretion and metabolism tests shall be conducted with 1,1-dichloroethylene in accordance with § 798.7475 of this chapter.

(B) Modifications. The following modifications to § 798.7475 of this chapter are required.

(*1*) *Species.* The requirement under § 798.7475(c)(1)(i) shall be modified so that 1,1-dichloroethylene shall be tested in two strains of mice, the "Swiss" mouse used by Maltoni et al. (1985) as cited under paragraph (d) of this section and the B6C3F$_1$ strain of mouse.

(*2*) *Age.* The requirement under § 798.7475(c)(1)(ii) is modified so that 1,1-dichloroethylene shall be tested in mice 6 to 8 weeks old.

(*3*) *Animal care.* The requirement under § 798.7475(c)(1)(iii) is modified so that food and water are provided *ad libitum*, except during the exposure period in the inhalation studies.

(*4*) *Kinetic studies.* The requirements under § 798.7475(c)(2)(iii) (B) (*1*), (*2*), and (*3*) are modified so that they are no longer required. This modification will also cancel the requirement under § 798.7475(c)(2)(iii)(D).

(*5*) *Repeated dosing study.* The requirement under § 798.7475(c)(2)(iii)(E) is modified so that the test species shall undergo repeated dosing by inhalation as well as by oral administration. Mice of both strains (4 animals from each sex) shall receive daily 6-hour exposure to non-radioactive test substance in air for 7 days, followed the next day by a 6-hour exposure to the radioactively by labeled test substance in air. Both high and low-dose levels shall be tested under each route of administration in each strain for each sex. Exposure to

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non-radioactive test substance shall be re-instituted following exposure to the label, and shall be continued until sacrifice.

(6) *Blood levels.* The requirement under § 798.7475(c)(3)(i) (A) is modified so that blod levels need by taken only at sacrifice.

(7) *Expired air, urinary and fecal excretion.* The requirement under § 798.7475(c)(3)(i)(B) is modified so that animals in the oral and inhalation repeated dosing studies shall be included. When collection of excreta is ended, the animals shall be sacrificed to determine tissue distribution of the label.

(8) *Tissue distribution.* The requirement under § 798.7475(c)(3)(i)(C) is modified to reduce the number of tissues and organs to be examined for ^{14}C-labeled compounds. Only the liver and kidney need to be checked. However, these tissues shall be analyzed to determine the ^{14}C-label's distribution within the cell, e.g., protein-bound, DNA-bound, or free in the cytoplasm.

(9) *Biotransformation.* The requirement under § 798.7475(c)(3)(ii) is modified to include all repeated dosing groups

(10) *Biotransformation changes.* The requirement under § 798.7475(c)(3)(iii) is modified to add the comparison of the ^{14}C-labeled components of urine collected at 24 and 48 hours after dosing group F, with that collected at similar times in the repeated inhalation dosing studies.

(11) *Test report.* The requirement under § 798.7475(d)(3)(v) is modified so that only the kidney and liver distribution and analysis shall be reported.

(ii) *Reporting requirements.* (A) The distribution, excretion and metabolism testing shall be completed and final results submitted to the Agency with 15 months of the effective date of the final rule.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule.

(2) *Oncogenic effects*—(i) *Required testing.* Oncogenicity tests shall be conducted in "Swiss" mice by inhalation with 1,1-dichloroethylene, in accordance with § 798.3300 of this chapter.

(ii) *Reporting requirements.* (A) The oncogenicity testing shall be completed and final results submitted to the Agency within 68 months of the effective date of the final rule.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule.

(d) *Reference.* Maltoni, C., Lefemine, G., Chieco, P., Cotti, G., Patella, V. *Experimental Research on Vinylidene Chloride Carcinogenesis.* Princetion, N.J.: Princetion Scientific Publishers, Inc. (1985).

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